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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,086	06/22/2001	Charles J. Matson	53963USA1A	3790

* 7590 11/29/2002

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EXAMINER

BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,086

Applicant(s)

MATSON ET AL.

Examiner

Rachel M. Bennett

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

The examiner acknowledges receipt of the IDS filed 8/1/01 and Election filed 10/7/02.

Election/Restrictions

1. Claims 1-7, 8-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 7.

Specification

2. The disclosure is objected to because of the following informalities: the text of amended sheets 2 and 2a does not continuously flow with the instant specification. The amended sheet must replace the original sheet, while maintaining continuity between pages. It is suggested applicants' submit newly amended sheets. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz (US 57501356), and further in view of Urry (US 5527610).

Scholz discloses a bioadhesive composition that adheres suitably to a mucosal surface and is capable of delivering drugs in sustained fashion. The bioadhesive composition comprises

- 1) a particulate polymeric resin with an average particle size of less than or equal to about 100 um and comprising at least about 55% by weight of carboxylic acid moieties based on the total

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of the polymeric resin; 2) from about 20 parts to about 250 parts by weight of a hydrophobic elastomeric component, based on 100 parts by weight of the resin and 3) an amount of a drug effective to provide a desired therapeutic results, wherein the resin and the drug are dispersed substantially throughout the elastomeric component and adheres to a mucosal surface. In a preferred embodiment when systemic treatment is desired, the bioadhesive composition has a backing such as a flexible film applied to it. Further, in yet another preferred embodiment the resin is crosslinked (see col. 2). The polymeric resin component may be linear polyacrylic acid resins with a molecular weight between about 400,000 and about 500,000. More preferred, however, are crosslinked resins. Particularly preferred resins of this type include resins available under the trade designation CARBOPOL™ resin (see col. 3 lines 19-53). By itself, a polymeric resin as described above generally possesses insufficient structural integrity. Such acidic resins can also be irritating to mucosal tissue. Further, a resin alone provides no means of controlled hydration and sustained release of drug. To remedy these deficiencies, the resin is substantially dispersed throughout a hydrophobic elastomeric compound. Examples of materials suitable for use in an elastomeric component include: polyolefins such as polyisobutylenes, polybutadienes, butyl rubber and isoprene rubber and mixtures and blends of two or more (see col. 4). Drugs that can be delivered include those useful for local treatment of the mouth or throat or vaginal cavity, in addition to those useful for systemic treatment via delivery through mucosal tissue. Practical limitations on the amount of drug incorporated in a composition are the amount above which the composition begins to lose adhesion to a mucosal surface. Generally, the preferred range is from about 0.1% to about 25% by weight based on the total weight of the bioadhesive composition (see cols. 6-7). Other ingredients, such as penetration enhancers, may also be added. Penetration

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enhancers have particular utility when used with drugs such as proteins or peptides. Specific penetration enhancers include glyceryl monolaurate (see col. 8, lines 5-21). Scholz does not specifically disclose the butyl rubber to be cross-linked or the specific drugs medetomidine or dexmedetomidine.

Urry discloses a bioelastomer comprising tetrapeptide and/or pentapeptide monomeric units of the formula I (see abstract). The bioelastomer can be uncrosslinked or crosslinked, depending on the manner of its ultimate use. For example, if the bioelastomer is used as a surface coating on a second material that provides appropriate mechanical properties, crosslinking is not necessary to provide mechanical strength. Cross-linking provides mechanical strength and rigidity to the polymer, and increasing amounts of cross-linking are appropriate for increasing demands of rigidity (see col. 5).

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the butyl rubber taught by Scholz by crosslinking the polymer to provide strength and rigidity to the polymer as taught by Urry. As for the specific pharmacological agents in claims 18 and 19, it is the position of the examiner it would be obvious to use any useful pharmacological agent, as indicated in both the instant application (see pages 9-11 of the specification) and in the above reference Scholz. Therefore, the examiner sees no criticality in the specific agents in claims 18 and 19.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett
November 25, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600